Immediate optimal endocrine adjuvant therapy versus standard chemotherapy followed by the same endocrine therapy in pre- or perimenopausal patients with early hormone receptor-positive breast cancer the PROMISE study.

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON25775

Source
NTR

Brief title
PROMISE, BOOG 2002-01

Health condition

breast cancer

Sponsors and support

Primary sponsor: BOOG
Source(s) of monetary or material Support: CKTO
AstraZeneca

Intervention

Outcome measures

Primary outcome

Relapse-free survival (RFS).

Secondary outcome

1. Overall survival (OS), the incidence of contralateral breast cancer;

2. Safety and longterm tolerability of both treatment regimens.

Study description

Background summary

N/A

Study objective

To compare the efficacy and tolerability of immediate optimal endocrine adjuvant therapy versus standard chemotherapy (5 endocrine therapy in pre- and perimenopausal patients with ER and/or PR courses FE90C) followed by the same positive primary breast cancer.

Intervention

arm A: goserelin + anastrozole for 5 years (experimental arm)

B: 5 courses of FEC90 followed by goserelin + anastrozole for 5 years
Goserelin is available as 4-weeks depot (Zoladex 3.6 mg) and as 3-month depot (Zoladex 10.8 mg). Zoladex 3.6 mg depot will be administered subcutaneously every 28 days.
The Zoladex 10.8 mg depot will be administered every 12 weeks.
Anastrozole 1 mg/day
FEC90 (standard dose, day 1, every 21 days):

- Cyclophosphamide 500 mg/m2 i.v. (push)

- Epidoxorubicine 90 mg/m2 i.v. (push)

- 5-Fluorouracil 500 mg/m2 i.v. (push)

Contacts

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Eligibility criteria

Inclusion criteria

1.. Pre-/perimenopausal patients aged less than 60 years at entry of the trial. Patients must have had their last menstrual period less than 2 years before surgery of the primary tumor. In previously hysterectomised patients, women with both postmenopausal plasma FSH and estradiol concentrations will be excluded;

2.
a. Any N+ subgroup (N1-3, N4-9, N□10);
b. Any high-risk N0 subgroup which meets one of the following criteria:

b1. Tumor size >= 3 cm;

b2 Tumor size 2-3 cm with grade II or III;

b3.Tumor size 1-2 cm with grade III;

b4. Patients < 35 years of age (with exception in case of tumors ≤ 1 cm, grade I);

3. ER or PgR receptor status positive as defined by local hospital criteria (as cut-off levels are adviced minimally >= 10% positively staining tumor cell by immunohistochemistry or >= 10 fmol/mg protein by ligand binding assay). ER-positive, PgR-negative patients are eligible;

4. Patients with either Her2/neu negative or positive tumors are eligible;

5. No previous systemic therapy for breast cancer;

6. Adequate hematological-, renal- and hepatic function (defined as PLT > 100x109/L, WBC > 3x 10 9/L, Creatinine< 1.5 UNL and SGOT (ASAT) or SGPT (ALAT) < 2.5 UNL);

7. Accessible for follow-up for the duration of the trial;

8.ECOG performance status 0 or1 (appendix II);

9. Written informed consent (according to ICH/GCP and local IRB guidelines).

Exclusion criteria

Those patients who did not undergo intended curative primary treatment or who fulfilled one of the following criteria:

1. Inflammatory breast cancer;

2. Positive supraclavicular nodes;

3. Ulceration/infiltration of local skin metastasis;

4. Primary surgery was completed more than 12 weeks before starting the randomised treatment;

5. Both ER negative and PgR negative primary tumor;

6. Evidence of distant metastases (M1);

7. Patients who have received previous systemic endocrine and/or chemotherapeutic treatment for breast cancer;

8. Uncontrolled cardiac disease including unstable angina, CHF or arrhythmia requiring medical therapy or with a history of myocardial infarction within the past 3 months or any other serious concomitant disease;

9. Psychiatric disorders preventing proper informed consent;

10. Tumor with a size < 1cm and N0 and age > 35 years;

11. Tumor size 1-2 cm, N0 with grade I or II and age > 35 years;

12. Tumor size 2-3 cm, N0 with grade I and age > 35 years;

13. Concomitant malignancies except for adequately treated carcinoma in situ of the uterine

cervix or basal squamous cell carcinoma of the skin, unless agreed by the Steering Committee. Subjects with other malignancies must be disease-free for at least 5 years. Patients with a history of breast cancer should be excluded;

14. Other serious illnesses that may interfere with subject compliance, adequate informed consent or determination of causality of adverse events;

15. Patients who are using contraceptive pills or receiving any HRT for treatment of peri-/postmenopausal symptoms should stop taking these endocrine agents at least 4 weeks prior to randomization;

16. Pregnancy or breast feeding;

17. In case a germline BRCA1 or BRCA2 mutation is known in the family of the patient, it is adviced not to include such patient in the study because of the different management of these patients and the increased risks of contralateral breast cancer and ovarian cancer (it is not warranted to perform standardly a DNA-test within the context of this trial).

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-07-2005
Enrollment:	25
Type:	Anticipated

Ethics review

Positive opinion

Date:	12-09-2005

Application type: First submission

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL319
NTR-old	NTR357
Other	: N/A
ISRCTN	ISRCTN23561723

Study results

Summary results
N/A